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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID K. KOVALIC and JINGDONG LIU

Appeal 2008-2230
Application 09/684,016
Technology Center 1600

Decided: September 24, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,
Administrative Patent Judges.

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 11-16, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims on appeal are directed to a substantially purified nucleic acid molecule. Claims 11, 13 and 14 are illustrative:

11. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411.

13. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof.

14. A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with nucleotides 1 through 123 of SEQ ID NO: 48411 or a complete complement thereof.

The Examiner relies on the following prior art reference to show unpatentability:¹

Mahairas et al., GenEMBL Acc. No. AQ451805.

¹ We find the Examiner's assertion that "[n]o evidence is relied upon by the Examiner in the rejection of the claims under appeal" to be in error. Nevertheless, because Appellants specifically addressed the reference relied upon by the Examiner, we find this error harmless (*see* App. Br. 20-21).

The rejections as presented by the Examiner are as follows²:

1. Claims 11-16 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.
2. Claims 11-15 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.
3. Claim 13 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Mahairas.

We affirm the rejections under 35 U.S.C. § 101 and under the enablement provision of 35 U.S.C. § 112, first paragraph. We also affirm the rejection under 35 U.S.C. § 102(b). We reverse the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

DISCUSSION

Utility:

Claims 11-16 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph, based on the finding of lack of utility.³ The claims have not been argued separately and, therefore, stand or fall together.

² While the Examiner discusses a rejection of claim 14 under the written description provision of 35 U.S.C. § 112, first paragraph, as containing new matter (Ans. 7), the Examiner later expressly withdrew this rejection “upon reconsideration” (Ans. 22).

³ The Examiner rejected the claims under both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However, the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility (*see* Ans.

37 C.F.R. § 41.37(c)(1)(vii). Therefore, we limit our discussion to representative claim 11.

Claim 11 is drawn to a substantially purified⁴ nucleic acid molecule. The nucleic acid molecule comprises a fragment of a nucleic acid molecule having from about 30 to about 50 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411.

Initially, we recognize that Appellants' Specification discloses "substantially purified nucleic acid molecule[s] where the nucleic acid molecule[s] comprise[] a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 463,173 or complements thereof or fragments of either" (Spec. 3:12-14). According to Appellants' Specification:

Agents of the present invention include plant nucleic acid molecules and more preferably include maize, soybean, cotton, sorghum, teosinte, wheat, and rice nucleic acid molecules.

4-5). Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

⁴ Appellants' Specification discloses that:

The term "substantially purified," as used herein, refers to a molecule separated from substantially all other molecules normally associated with it in its native state. More preferably a substantially purified molecule is the predominant species present in a preparation. A substantially purified molecule may be greater than 60% free, preferably 75% free, more preferably 90% free, and most preferably 95% free from the other molecules (exclusive of solvent) present in the natural mixture. The term "substantially purified" is not intended to encompass molecules present in their native state.

(Spec. 9:3-9.)

A subset of the nucleic acid molecules of the present invention includes nucleic acid molecules that are marker molecules. Another subset of the nucleic acid molecules of the present invention includes nucleic acid molecules that encode a protein or fragment thereof. Another subset of the nucleic acid molecules of the present invention is cDNA molecules.

(Spec. 8:22-27.) While claim 11 is drawn to a substantially purified nucleic acid molecule comprising a nucleic acid molecule having from about 30 to about 50 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411, Appellants fail to disclose which subset of nucleic acid molecules, if any, SEQ ID NO: 48411 is a member (*Cf. id.*). In this regard, we note that apart from a listing of its sequence, SEQ ID NO: 48411 remains uncharacterized.

Nevertheless, Appellants assert that the claimed nucleic acid can be used to identify the presence or absence of polymorphisms, to measure the level of mRNA in a sample, as molecular markers, to isolate nucleic acid homologues of other plants and organisms, to isolate or identify the promoter of the gene corresponding to that claimed nucleic acid molecule, and to perform high-throughput microarray analysis of expression changes in a series of tissue samples (App. Br. 7-10 and 12 (footnotes omitted)).

However, as the Examiner explains, “the Specification summarized pretty much the [state of the art in] modern biotechnology in general, but never connects . . . [SEQ ID NO: 48411] to any particular or specific utility. This wishlist-like [sic] desire for a utility for the claimed sequences seems to fall short of a readily available utility” (Ans. 3-4). We find no error in the Examiner’s conclusion that Appellants have not satisfied the utility

requirement for the claimed nucleic, which - but for its sequence - remains uncharacterized.

Here, as in *In re Fisher*, 421 F.3d 1365, 1374 (Fed. Cir. 2005) nothing about Appellants' alleged uses set a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 48411 or its complement apart from any of the other 463,172 sequences disclosed in Appellants' Specification. Accordingly, we conclude, as did the court in *Fisher*, that Appellants have only disclosed general uses for their claimed nucleic acid molecule, not specific ones that satisfy § 101. *Cf. id.*

For the foregoing reasons, we affirm the rejection of claim 11 under 35 U.S.C. § 101, and the enablement provision of 35 U.S.C. § 112, first paragraph. As they are not separately argued, claims 12-16 fall together with claim 11.

Written Description:

Claims 11-15 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

The rejection is based on the Examiner's concern that Appellants' use of the transitional term "comprising" results in claims drawn to a large genus of nucleic acid molecules which are not adequately described by Appellants' Specification. (Ans. 5-7). We disagree.

As Appellants explain, they have fully described the nucleotide sequence of SEQ ID NO: 48411 (App. Br. 17). We agree. All the claims before us on appeal are drawn to a nucleic acid molecule that has the nucleic acid sequence of SEQ ID NO: 48411 or a complete complement thereof, a fragment or complement of a fragment of the nucleic acid molecule defined

by SEQ ID NO: 48411, or has between 90-100% or 99-100% sequence identity with nucleotides 1-123 of SEQ ID NO: 48411 or a complete complement thereof.

No doubt, the use of the transitional term “comprising⁵” opens the claims to read on a nucleic acid molecules that include more than SEQ ID NO:48411, or a fragment thereof, e.g., a fragment of SEQ ID NO: 48411 in an expression vector. However, all members of the genus will include a common structural feature that is described in Appellants’ Specification. Specifically, all members of the genus will include a fragment of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a nucleic acid molecule, or fragment thereof, having some level of sequence identity with the nucleotide sequence of SEQ ID NO: 48411. One of ordinary skill in this art would recognize that Appellants were in possession of this common structural feature of all the members within the genus encompassed by the claims. *See e.g.*, Written Description Training Materials 13-14 (rev. 1 March 25, 2008) (<http://www.uspto.gov/web/menu/written.pdf>).

Accordingly, we agree with Appellants that they have provided an adequate written description of nucleic acid molecules set forth in their claims. Therefore, we reverse the rejection of claims 11-16 under the written description provision of 35 U.S.C. § 112, first paragraph.

⁵ We note that the Examiner appears to have interpreted the term “having” as it appears in claims 14 and 15 to mean “comprising. *See, e.g., Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term “having” was interpreted as open terminology, allowing the inclusion of other components in addition to those recited).

Anticipation:

Claim 13 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Mahairas.

Claim 13 is drawn to a substantially purified nucleic acid molecule. The claimed nucleic acid molecule comprises a fragment of a nucleic acid molecule that:

1. has from about 30 to about 50 nucleotide residues and
2. exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof.

According to Appellants' Specification, "molecules are said to be 'complementary' if they can hybridize to one another with sufficient stability to permit them to remain annealed to one another under conventional 'high-stringency' conditions" (Spec. 10: 6-8). Appellants' Specification discloses that "[a] nucleic acid molecule is said to be the 'complement' of another nucleic acid molecule if they exhibit complete complementarity" (Spec. 9: 30 - 10: 2). "As used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other" (Spec. 10: 2-4).

Therefore, while the claimed nucleic acid molecule may be of any length larger than about 30 nucleotides, claim 13 places two structural requirements on the claimed nucleotide sequence. Specifically, the claimed nucleic acid molecule must comprise (1) a fragment of a specific size (about 30 to about 50 nucleotides) and (2) a specific sequence (one wherein every nucleotide of the fragment of the claimed nucleic acid molecule is complementary to a fragment of a second nucleic acid molecule that has the

nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof).

Mahairas teaches a nucleic acid molecule that is 349 nucleotides in length (Mahairas). Appellants do not dispute, and therefore concede,⁶ that Mahairas' nucleic acid molecule comprises a 21 nucleotide fragment that exhibits complete complementarity to a 21 nucleotide fragment of a second nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof (*id.*; *see also* Ans. 8). Instead, Appellants assert that the fragment taught by Mahairas falls outside the scope of the about 30 to about 50 nucleotide residue size limitation set forth in claim 13 (App. Br. 21).

In essence, the issue present is whether the term “about 30” reads on a nucleotide fragment of 21 nucleotides in length. Notwithstanding, Appellants' assertion to the contrary, we find that the preponderance of the evidence on this record supports a conclusion that it does.

According to Appellants, “the term ‘about’ in the present claims should be given its ‘plain and ordinary meaning’” (App. Br. 21 (*citing BJ Services Co. v. Haliburton Energy Services, Inc.*, 338 F.3d 1368, 1373 (Fed. Cir. 2003))). In this regard, Appellants assert that a “21 nucleotide base pair fragment fails to give ‘about 30 nucleotides’ its ‘plain and ordinary meaning’” (*id.*). Appellants do not, however, direct our attention to any portion of their Specification, the prosecution history of this application, or extrinsic evidence to support this assertion.

⁶ Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) (“Any arguments or authorities not included in the brief or a reply brief . . . will be refused consideration by the Board, unless good cause is shown.”).

“The use of the word ‘about,’ avoids a strict numerical boundary to the specified parameter.” *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007); see also *In re Harris*, 409 F.3d 1339, 1343 (Fed. Cir. 2005) (“[U]se of the term ‘about’ shows that the applicants did not intend to limit the claimed ranges to their exact end-points”); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 2005) (“[T]he word ‘about’ does not have a universal meaning in patent claims[.]” rather, “the meaning depends on the technological facts of the particular case”); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995) (“The meaning of the word ‘about’ is dependent on the facts of the case, the nature of the invention, and the knowledge imparted by the totality of the . . . disclosure to those skilled in the art.”).

Upon consideration of claim 13 in light of Appellants’ Specification, we find that a person of ordinary skill in this art would reasonably interpret the term “about” broadly as it relates to the fragment length of Appellants’ claimed nucleic acid molecule. In this regard, we note that Appellants’ Specification discloses nucleic acid molecule fragments of about 15 to about 250 nucleotide residues (Spec. 8: 29-30). In addition, Appellants’ Specification discloses two additional, yet overlapping fragment size ranges - about 15 to about 30 nucleotide residues and about 30 to about 50 nucleotide residues⁷ (Spec. 8: 30 - 9: 1).

Considering the two overlapping ranges, it is clear that Appellants have disclosed a lower (about 15) and an upper (about 50) limit. The issue

⁷ Appellants’ Specification also discloses a second set of overlapping ranges from about 30 to about 50 nucleotide residues and about 50 to about 100 nucleotide residues (Spec. 9: 1-2).

we are faced with, however, is how a person of ordinary skill in this art would interpret the intermediate fragment size of about 30 in view of Appellants' disclosure and the conventional knowledge in this art at the time the invention was made. Stated differently, how many additional nucleotides on either side of 30 are included by the term "about"?

The Examiner interprets the range "from about 30 to about 50" to include a fragment with nine fewer nucleotides, e.g., a 21 nucleotide fragment that exhibits complete complementary to a fragment of a second nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof as is taught by Mehaires.

For their part, Appellants fail to identify any disclosure in their Specification to suggest that 21 nucleotides does not fall within the scope of about 30 nucleotides. Similarly, Appellants offer no evidence to suggest that a person of ordinary skill in this art would not reasonably interpret the term about 30 as reading on a 21 nucleotide fragment. Instead, Appellants simply provide an unsupported assertion that "21 nucleotides fails to give 'about 30 nucleotides' its 'plain and ordinary meaning'" in this art (App. Br. 21). We are not persuaded by this unsupported assertion or Appellants' reliance on *BJ Services*. Claim 5 at issue in *BJ Services* was drawn to a method of fracturing a subterranean formation. One step in the claimed method required, *inter alia*, a hydratable polymer blend "wherein the hydratable polymer [had] . . . a C* value of about 0.06 percent by weight" (*BJ Services*, 338 F.3d at 1370).

BJ Services argue[d] that the term "about" is intended to encompass the range of experimental error that occurs in any measurement and that one of skill in the art would readily understand the range that "about 0.06" was intended to include.

To that end, it presented the experimental results obtained by its expert, all of which were slightly above or below 0.06 for an average of 0.0596.

(*Id.*, at 1372.) Halliburton “agreed that the jury should be instructed to give ‘about 0.06’ its plain and ordinary meaning” (*id.*, at 1373). Therefore, our appellate reviewing court concluded that “[g]iven that the term ‘about’ was used to encompass experimental error and that the jury had before it the typical experimental range, substantial evidence support[ed] the jury’s finding” (*id.*).

On this record, it is clear that the term “about” refers to the length of a nucleic acid molecule fragment. There is, however, no evidence on this record to support Appellants’ contention that a fragment of “about 30” nucleotides does not include 21 nucleotides.

It may be that Appellants intend the phrase “from about 30 to about 50” to mean from 30 or more to 50 or less. In this scenerio, a range from about 15 to about 30 would be interpreted as meaning from 15 or more to 30 or less. The problem, however, is that if this was Appellants’ intention, their claim, Specification, and arguments fail to articulate such an interpretation.

Accordingly, absent evidence to the contrary, we affirm the rejection of claim 13 under 35 U.S.C. § 102(b) as being anticipated by Mahairas.

CONCLUSION

In summary, we affirm the rejections under 35 U.S.C. § 101 and under the enablement provision of 35 U.S.C. § 112, first paragraph. We also

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affirm the rejection under 35 U.S.C. § 102(b). We reverse the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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